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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,271	03/11/2002	Jean-Louis Ruelle	BM45323	8726
25308	7590	09/02/2004	EXAMINER	
DECHERT ATTN: ALLEN BLOOM, ESQ 4000 BELL ATLANTIC TOWER 1717 ARCH STREET PHILADELPHIA, PA 19103			BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/701,271

Applicant(s)

RUELLE ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31,38,39,60-62 and 65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 31,39,60-62 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicant's amendment filed on 5/8/04 is acknowledged.

#### ***Status of Claims***

2. Claims 36-37, 68-69 and 71 have been canceled.

Claims 31, 39, 60, 62 and 65 have been amended.

Claims 31, 38-39, 60-62 and 65 are pending in the application.

#### ***Claim Rejections - 35 USC 112, second paragraph withdrawn***

3. In view of amendment to the claims the rejection under 35 U.S.C. 112, second paragraph is withdrawn.

#### ***Claim Rejections - 35 USC 102 withdrawn***

4. In view of amendment to the claims, the arguments of record and cancellation of claims, the rejection of claims 31 and 71 under 35 U.S.C. 102(b) as being anticipated by Tonjum et al 1998 Accession number: Q9ZHF3 is withdrawn as the prior art does not disclose an isolated recombinant polypeptide comprising the amino acid sequence SEQ.ID.NO: 2.

5. In view of amendment to the claims, the arguments of record and cancellation of claims, the rejection of claims 31 and 71 under 35 U.S.C. 102(b) as being anticipated by Drake et al 1995 (Accession number: Q50972) is withdrawn as the prior art does not disclose an isolated recombinant polypeptide comprising the amino acid sequence SEQ.ID.NO: 2.

#### ***Claim Rejection - 35 USC 102 maintained***

6. The rejection of claims 31, 39, 60-62 and 65 under 35 U.S.C. 102(b) as being anticipated by Martin et al 1997 (J.Ex.Med. Volume 185, Number 7, April 7, 1997 1173-1184) is maintained as set forth in the previous office action.

Claims are directed to an isolated polypeptide or immunogenic composition, fusion protein comprising the amino acid sequence, SEQ.ID.NO: 2. Claims are also drawn to a method of inducing an immune response comprising administration of said polypeptide.

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Martin et al disclose an isolated polypeptide, outer membrane polypeptide from whole cell lysate of OM preparations from various clinical isolates including nine meningococcal strains two of serogroup A (604A and Z4063), one of serogroup B (608B [B: 2a:P1.2: L3]), two of serogroup C (2241C and 59C), one of serogroup 29-E, one of serogroup W-135, one of serogroup Y (SLATY) and one of serogroup Z (SLATZ) (page 1174, under materials and method, antigens). Monoclonal antibodies were produced by immunizing mice with OM preparation indicating that the disclosed isolated polypeptide are immunogenic and thus read on claim 43. Applicant's use of the open-ended term "comprising " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Whole cell lysates prepared in buffer (pharmaceutical carrier) from *N.meningitidis* inherently comprise SEQ.ID.NO: 2 and several *N.meningitidis* antigens in the form of fusion proteins. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the claimed isolated polypeptide-comprising SEQ.ID.NO: 2 is inherent in the preparations of the disclosed prior art polypeptide. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2, with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments filed on 5/8/04 have been fully considered but they are not deemed to be persuasive.

Applicant states that, Applicants have amended claims 31,39, 60, 62 and 65 to recite an isolated, recombinant polypeptide. The claimed isolate is not disclosed or suggested by the OM preparations described in Martin et al. Accordingly, reconsideration of the rejection is respectfully requested.

The examiner disagrees with the applicant because by amending the claim to recite "recombinant" will not make the product different from that of the disclosed isolated outer membrane proteins. Applicant did not provide any evidence to show that the claimed polypeptide is different from the disclosed polypeptide of Martin et al.

Further, the transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See

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Molecular Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In re Gray, 53 F. 2d 520, 11 USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948). Therefore, the examiner has allowed the claim 38. However, claim 39 is not limited to SEQ.ID.NO: 2 and also contains unknown and unlimited polypeptides. Therefore, the disclosed polypeptide read on the claimed invention.

In addition, product-by-process claims are limited and defined by the process, nonetheless, determination of patentability is based on the product itself. The patentability of a product does not depend upon its method of production. If the product in the product-by-process claim is the same as or an obvious variant of the product of the prior art, the claim is unpatentable even though the product was made by a different process. The recitation of a process limitation in claim "recombinant" is not seen as further limiting the claimed product, as it is presumed the equivalent products can be obtained by multiple routes. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. In re Thorpe, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). In re Marosi, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). In re Best, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). In re Brown, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

Applicant is advised that the process limitations cannot be relied upon for patentability and that the patentability of the subject matter is being assessed based upon the product and it's

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attendant properties. In re Marosi, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983). Scripps Clinic & Res. Found. v. Genentech, Inc., 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). Therefore, this rejection is maintained.

**Remarks**

7. Claims 31,39, 60-62 and 65 are rejected.  
Claim 38 is allowed.

**Conclusion**

8. THIS ACTION IS MADE FINAL. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

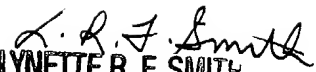
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

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13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar

  
LYNETTE R. F. SMITH  
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